REMARKS

Applicant respectfully requests reconsideration. Claims 1-10, 15-16, and 19-24 were previously pending in this application. Claims 15, 16, 21, and 22 have been withdrawn. Claims 1 and 10 have been amended. Claim 3 has been cancelled. New claims 25 and 26 have been added, which recite subject matter previously recited in claims 1 and 3 prior to amendment/cancellation. Nowhere does the prior art of record appear to teach or suggest all of the limitations of new claims 25 and 26; therefore, these claims are believed to be patentable over the prior art of record. Claims 1-2, 4-10, 19-20, 23, 26 and 26 are pending for examination. No new matter has been added.

Claim 1 has been amended to delete the objected to term "possibly substituted," and incorporate certain limitations from claim 3, now cancelled, to further define the meaning of "saturated and unsaturated heterocycle" also objected to in the previous Office Action.

In all instances herein where reference to the specification of the instant application is made, reference is made to the corresponding published U.S. patent application (U.S. Patent Publication US 2006/0040914).

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Patent Office has objected to the terms "possibly," "substituted" and "heterocycle/heterocyclic" as rendering the claim indefinite.

At the outset, Applicants believe that the above language references the scope of the claims sufficiently clear to be understandable to those skilled in the art, which is all that is required to satisfy 35 U.S.C. 112, second paragraph. For example, the terms "substituted, heterocycle and heterocyclic" are believed to have a well understood, clear meaning in the chemical arts. The comments in the Office Action appear to object to the scope of coverage implied by these recitations rather than the clarity and understandability of their meaning to those skilled in the art.

However, as is clear in the caselaw and MPEP, breadth of a claim is not to be equated with indefiniteness.[1]

Nevertheless, solely to expedite allowance, Applicant has amended independent claim 1, without prejudice, to delete "possibly substituted" and "comprising up to two heteroatoms selected from the group consisting of N, O and S" and instead recite that the structures are selected from those previously recited in dependent claim 3, which is now cancelled.

Accordingly, since it is believed that the current amendments to claim 1 render the rejection now moot, withdrawal of the rejection of claims 1-2 and 4-10 on this basis is respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 19-20 and 23-24 are directed to a method of sterilizing wounds and treating viral, fungal bacterial diseases characterized by cellular hyperproliferation and dermatological diseases. According to the Patent Office, the application fails to provide an enabling disclosure for the full scope of the claimed subject matter. (Office Action on page 7.) Applicant respectfully traverses the rejection.

Applicant notes that the Patent Office must consider not just a single factor, but a totality of the circumstances involving many factors when making a determination that the application is not enabled.[2] Applicant submits that an analysis of the *Wands* factors weighs in favor of Applicant's assertion of enablement over the full scope of the claims, as discussed in detail below.

Breadth of the Claims

The breadth of the claims is reasonable in view of the teaching in the specification, as described further below in view of the other *Wands* factors. Applicant disagrees with the assertion by the Patent Office that Applicant has failed to exactly define what types of wounds and viral, fungal, and bacterial diseases characterized by cellular hyperproliferation, and dermatological diseases are treated. With respect to the types of wounds treated, Applicant points out that instant

[1] "If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with **35 U.S.C. 112**, second paragraph." Quoting MPEP 2173.04.
[2] *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

claim 23 is directed to a method of *sterilizing* wounds, which merely requires that one of skill in the art select wounds for treatment that benefit from sterilization. (Emphasis added.) The types of wounds benefiting from sterilization are well-known in the art (i.e., wounds that are infected or prone to infection), and one of ordinary skill in the art would be able to identify such wounds readily. For example, the specification in paragraph [0045] discloses that the compounds of the instant application can be used to treat anaerobic micro-organisms. Those of skill in the art would recognize that anaerobic micro-organisms (i.e., *Clostridium tetani*, the micro-organism that causes tetanus) can infect hypoxic wounds such as puncture wounds and thus would know to use the compounds of the instant application to treat such wounds. In regards to the diseases characterized by cellular hyperproliferation and dermatological diseases, such diseases are well-known to those of ordinary skill in the art and can be recognized by the hyperproliferative characteristic of the diseases. Examples of diseases characterized by cellular hyperproliferation and dermatological diseases include psoriasis, actinic keratoses, basal cell carcinomas, atheromas, endoarterial hyperplasia, prostate hyperplasia, other cancerous and pre-cancerous lesions of the skin and mucosas, as well as infections caused by pathogenic micro-organisms, including bacterial and mycotic infections, as disclosed in the specification in paragraphs [0005], [0012], and [0013]. While independent claims 19 and 23 are not limited to the treatment of one, specific disease or type of wound, those of ordinary skill in the art would easily be able to select, without undue experimentation, a disease or type of wound suitable for treatment by a compound of the present invention.

The Nature of the Invention

The nature of the invention is a method of treating infectious diseases of viral, fungine and bacterial origin and treating diseases characterized by cellular hyperproliferation and dermatological diseases. The compound may be administered by methods known to those of ordinary skill in the art, in view of the teachings of the specification and the prior art. As noted above, the diseases to be treated may be characterized by cellular hyperproliferation and dermatological diseases.

The State of the Prior Art

The state of the prior art is advanced. Applicant describes the state of the art in the specification and indicates that photodynamic therapy (PDT) has been used previously for the treatment of hyperproliferative diseases and microbial photoinactivation (please see, for example, paragraphs [0002]-[0006] of the specification). The references submitted herewith also indicate that, at the time the application was filed, PDT was a well-recognized therapy or candidate therapy for treatment of diseases characterized by cellular hyperproliferation [see, for example, Tetrahedron (1998), page 4160 (excerpt attached), and Journal of Antimicrobial Chemotherapy (1998), page 24]. These references further indicate that a number of compounds are FDA-approved for photodynamic therapy and provide clinical characteristics including the mode of delivery of the drug, the delivery vehicle, the typical dose, etc. [see, for example, DDT (2000), page 509, submitted herewith (the "DDT reference")].

The Level of Ordinary Skill in the Art

The level of ordinary skill in the art is high. The relevant arts include organic chemistry, medicinal chemistry, and the treatment of infections as well as prevention of infection as well as conditions including skin diseases and cancer. The skilled artisan is generally familiar with routine methods for preparing pharmaceutical compositions comprising porphyrin photosensitizing compounds, administration of the compositions, and activation of the compositions [see, for example, DDT page 509, which discloses clinical characteristics for several porphyrin photosensitizing compounds].

The Level of Predictability of the Art

The Patent Office asserts that the treatment of wounds and viral, fungal, bacterial diseases and diseases characterized by cellular hyperproliferation and dermatological diseases is highly unpredictable.

Applicant respectfully disagrees that, in view of the state of the art and applicants teaching, this factor weighs against enablement. Applicant notes that the specification teaches a class of molecules: meso-substituted porphyrins for use in PDT, as well as a number of specific conditions to be treated using this class of molecules. The general effectiveness of PDT in connection with

such specific conditions is known [see, for example, the references submitted herewith]. Furthermore, assays and screening tests that can be used to determine whether the claimed porphyrins can be useful in treating or managing the claimed conditions are known in the art. Thus, one of skill in the art, in view of the methods disclosed in the references submitted herewith, and using the inventive compounds to treat or manage the specific conditions disclosed in the invention, would be able to determine, without undue experimentation, whether and to what extent a given porphyrin within the scope of the present claims would be effective in treating such conditions.

The Amount of Direction Provided

The amount of direction provided by the Applicant in the specification is substantial. The specification (see, for example, paragraph [0049]) and the prior art provide various techniques that are applicable to methods for screening and administration of such compounds. Administration profiles and combination ratios of the active agents would able to be readily determined by those of ordinary skill in the art based on the specification, further in view of data in the prior art. For example, as discussed above, the DDT reference provides fundamental clinical characteristics for PDT such as activation wavelength, mode of delivery of the drug, the delivery vehicle, the typical dose of compound, light dose, etc. One of skill in the art could readily determine the effective level of each of these characteristics by routine experimentation based on this information.

The Existence of Working Examples

The existence of working examples is not a necessary requirement to establish whether or not undue experimentation would be needed to practice the claimed invention. As discussed herein, the specification, in combination with the prior art, is believed to provide enough information for one of skill in the art to make and use the claimed invention.

The Quantity of Experimentation Needed

The amount of experimentation required to practice within the scope of the claims that stand rejected on this ground, in view of the totality of teachings of the specification of this application and the state of the art, is believed to be no more than routine experimentation. Applicant

respectfully disagrees that it would be necessary to show a vast range of different types of wounds and viral, fungal, and bacterial diseases characterized by cellular hyperproliferation and dermatological diseases that could be treated for enablement. As noted above, because of the cytotoxic properties of the compounds disclosed in the specification, the compounds would be expected to be useful for treating any wound that is infected or prone to infection by essentially any viral, fungal, and bacterial disease characterized by cellular hyperproliferation and dermatological disease. The mechanism of action of the compounds is general in that microbes and other hyperproliferative cells are targeted by the compounds (see, for example, paragraph [0005] and [0047], of the specification). Screening of the claimed compounds for their effectiveness in treatment or management of specific conditions and determining the effective dose therefore would involve routine experimentation since these parameters have been disclosed previously for other similar photodynamic therapeutics [see, for example, the DDT reference]. One of skill in the art, having knowledge of these parameters, could readily determine the dosage for the compounds disclosed in the specification for a particular application using the type of routine experimentation conventional in the medicinal arts. A survey of the prior art (references included in the specification, of record in the present application, and submitted herewith) provides evidence of the fact that such methods in general are known to those skilled in the art.

Therefore, a full and fair analysis of the *Wands* factors strongly suggests that the Applicant has enabled the claimed invention throughout its full scope.

Accordingly, withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Rejections Under 35 U.S.C. § 102(b) and § 103(a)

a. Claims 1-10 are rejected under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) as being anticipated by and unpatentable over Li et al. (Liquid Crystals 2000) ("Li").

Without conceding the merits of the rejections, the Applicant has amended independent claim 1, without prejudice, to even further distinguish the claimed invention from Li in order to expedite allowance. For example, amended independent claim 1 now recites that "Y is selected from aliphatic groups, linear or branched, saturated or unsaturated, having from 1 to 10 carbon

atoms, and phenyl, *or Y forms with Z a saturated or unsaturated heterocycle, selected from the group consisting of morpholine, piperidine, pyridine, pyrimidine, piperazine, pyrrolidine, pyrroline, aniline and julolidine (2,3,6,7-tetrahydro-1H,5H-pirido[3,2,1-Ij] quinoline).*" By contrast, Li appears to be limited to compounds, wherein any structure that could be construed as corresponding or analogous to Y forms with any structure that could be construed as corresponding or analogous to Z only a benzothiazole heterocycle or an imidazole heterocycle. Nowhere does Li appear to disclose or suggest a compound of general formula (I) of amended independent claim 1 with an R group as formula (II), wherein Y is selected from aliphatic groups, linear or branched, saturated or unsaturated, having from 1 to 10 carbon atoms, and phenyl, or Y forms with Z a saturated or unsaturated heterocycle, selected from the group consisting of morpholine, piperidine, pyridine, pyrimidine, piperazine, pyrrolidine, pyrroline, aniline and julolidine (2,3,6,7-tetrahydro-1H,5H-pirido[3,2,1-Ij] quinoline), nor does Li appear to provide any reason, motivation or direction to the skilled artisan to make the modifications necessary to the compounds of Li to arrive at the compounds covered by independent claim 1, as amended. Indeed, the Office Action itself appears to be silent regarding any reason for modification and relies simply on an alleged structural overlap. Amended claim 1 and the compounds disclosed by Li are not believed to be structurally overlapping.

Additionally, claim 1 has also been amended to further limit the compounds to those "effective for the treatment of at least one of: infectious diseases of viral, fungine and bacterial origin, diseases characterized by cellular hyperproliferation, and dermatological diseases upon irradiation with light of appropriate wavelength." Li in stark contrast is directed to porphyrinatozinc(II) compounds for doping liquid crystals and does not disclose or suggest that any of the compounds would be effective for the treatment of infectious diseases of viral, fungine and bacterial origin, diseases characterized by cellular hyperproliferation, and dermatological diseases upon irradiation with light of appropriate wavelength. Furthermore, since Li is directed to liquid crystals and does not disclose any medical or biological activity for the compounds, Li would appear to provide no reason for one of ordinary skill in the art to modify or attempt to use such compounds for treatment of infectious diseases of viral, fungine and bacterial origin, diseases

characterized by cellular hyperproliferation, and dermatological diseases upon irradiation with light of appropriate wavelength, nor would it provide a reasonable expectation of success for doing so..

Thus, amended independent claim 1 should be patentable in view of Li. Claim 3 has been cancelled rendering the rejection of this claim moot. Claims 2 and 4-10 depend from claim 1 and therefore also should be patentable. Accordingly, withdrawal of the rejection of claims 1-2 and 4-10 on this basis is respectfully requested.

b. Claims 1-10 are rejected under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) as being anticipated by and unpatentable over Ito et al. (Chem. Soc. of Japan 2001) ("Ito").

Without conceding the merits of the rejections, the Applicant has amended independent claim 1, without prejudice, to even further distinguish the claimed invention from Ito in order to expedite allowance. Claim 1 as amended is believed to exclude any structural overlap with any of the compounds disclosed by Ito. Moreover, Ito does not appear to provide any reason, motivation or direction to the skilled artisan to make the modifications necessary to the compounds of Ito to arrive at the compounds covered by independent claim 1, as amended. Indeed, the Office Action itself appears to be silent regarding any reason for modification and relies simply on an alleged structural overlap. Amended claim 1 and the compounds disclosed by Ito are not believed to be structurally overlapping.

Additionally, amended independent claim 1 has also been amended to further limit the compounds to those "effective for the treatment of at least one of: infectious diseases of viral, fungine and bacterial origin, diseases characterized by cellular hyperproliferation, and dermatological diseases upon irradiation with light of appropriate wavelength." Ito in stark contrast is directed to an analysis of the effects of magnetic fields on the lifetimes of zinc(II) tetraphenylporphyrin-viologen biradicals. Nowhere does Ito disclose or suggest that zinc(II) tetraphenylporphyrin-viologen would be effective for the treatment of infectious diseases of viral, fungine and bacterial origin, diseases characterized by cellular hyperproliferation, and dermatological diseases upon irradiation with light of appropriate wavelength. Furthermore, given the lack of any disclosure by Ito concerning any medical or biological activity of zinc(II) tetraphenylporphyrin-viologen, Ito would appear to provide no reason for one of ordinary skill in

the art to modify or attempt to use such compounds for treatment of infectious diseases of viral, fungine and bacterial origin, diseases characterized by cellular hyperproliferation, and dermatological diseases upon irradiation with light of appropriate wavelength, nor would Ito provide a reasonable expectation of success for doing so.

Thus, amended independent claim 1 is thus believed to be patentable in view of Ito. Claim 3 has been cancelled rendering the rejection of this claim moot. Claims 2 and 4-10 depend from claim 1 and therefore are also believed to be patentable. Accordingly, withdrawal of the rejection of claims 1-2 and 4-10 over Ito is respectfully requested.

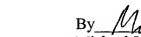
CONCLUSION

In view of the foregoing, this application should now be in condition for allowance. A notice to this effect is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. M1100.70002US00, from which the undersigned is authorized to draw.

Dated: September 8, 2009

Respectfully submitted,

By 

Michael J. Pomjanek, Ph.D.
Registration No.: 46,190
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
617.646.8000